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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Anders Nykjaer, et al.	Confirmation No. 6823	
Serial No.:	10/539,443	Examiner:	S. MacFarlane
Filed:	June 20, 2005	Group Art Unit:	1649
For:	MODULATION OF ACTIVITY OF NEUROTROPHINS		

APRIL 26, 2011

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT OF THE SUBSTANCE OF THE APRIL 25, 2011 INTERVIEW

Applicants respectfully request this Statement of the Substance of the April 25, 2011 Interview (the "Statement") with regard to the merits of the above-identified application be made of record. This Statement is being timely filed and a complete reply to the outstanding Office Action issued October 26, 2010 is also being filed on this day.

No fee is deemed necessary in connection with the filing of this Statement; however, if any fee is required, authorization is hereby given to charge the fee to Deposit Account No. 503201.

Summary begins on page 2 of this paper.
Remarks begin on page 3 of this paper.

SUMMARY

Interview:

(1) Interview date: April 25, 2011

(2) Interview type: Telephonic

Participants:

(3) Examiner(s): Stacey MacFarlane

(4) Applicant's Representative(s): Mary Johnson

Details:

(5) Claims discussed: All claims

(6) Discussion of the prior art:

- Harrington et al., *PNAS* 2004 April 20; 101(16): 6226-30
- Beattie et al., *Neuron* 2002 October 24; 36(3): 375-86

REMARKS

Substance of the Interview, including description of the general nature of what was agreed to, if any agreement was reached:

Applicants' representative offered Applicants' position and arguments with regard to the enablement rejection, as follows:

- the specification teaches a method of modulating pro-neurotrophin activity in an animal comprising administering to said animal a sufficient amount of an agent capable of
  (i) binding to a receptor of the Vps10p-domain receptor family
  and/or
  (ii) interfering with binding between a receptor of the Vps10p-domain receptor (see page 24, lines 24-31 of the specification);
- Applicants' claimed invention is specifically directed to a method of inhibiting the binding of pro-NGF to a sortilin receptor, and administering an inhibitorily effective amount of an antibody which binds to an extracellular part of the sortilin receptor. Dr. Castrén's Declaration provides evidence of an antibody directed to an extracellular domain of the sortilin receptor which interferes with binding of pro-NGF to such sortilin receptor. The Declaration of Dr. Castrén further provides evidence that interfering with the binding of pro-NGF to a sortilin receptor results in an increased survival of neurons in an animal model of spinal cord injury. The claimed method is carried out when neurons are damaged by trauma or surgery, as taught by the specification at page 32, lines 26-33, and evidenced by the Declaration;
- the rat model for spinal cord injury as described in the June 15, 2009 Declaration by Dr. Castrén, and referenced in Harrington et al (2004) therein, is not a new method and was known prior to the time of filing. (See Harrington at page 6226, bottom of column 1; and the references cited therein.) Applicants' specification further mentions the teachings of Beattie et al. (*Neuron* 2002 October 24; 36(3): 375-86), which scientific article describes a rat spinal cord injury model and use of anti-pro-NGF antibodies in such *in vivo* model;
- Applicants would amend claim 93 to read on "a method for inhibiting the binding of pro-NGF to a sortilin receptor wherein said method comprises administering an inhibitorily effective amount of an antibody which binds to an extracellular part of such receptor to an animal suffering from neurons that are damaged by trauma or surgery, thereby inhibiting the binding of pro-NGF to said receptor". Such amended claims would embrace a

reasonable scope which correlates with the teachings of the specification and the known art; and

- previously submitted evidence (*e.g.* the March 24, 2008 Declaration of Dr. Thomas Willnow) indicates that trauma, injury and/or disease compromises the integrity of the blood-brain-barrier (BBB), and therefore a reasonable expectation of success using the antibodies of the invention exists.

The Examiner acknowledged the prior art teachings that trauma or injury or disease in an animal may compromise the BBB and a reasonable use of antibodies exists during this compromised state.

The Examiner gave indication that the suggested amendments to claim 93 appeared to overcome the outstanding rejection made under 35 U.S.C. 112, first paragraph. The Examiner also suggested amending claim 94 to read ..."wherein the animal is human".

Applicants maintain that this Statement is complete and accurate regarding the substance of the April 25, 2011 Interview. Applicants respectfully request that the Examiner reviews this Statement and makes corrections to any material inaccuracies, if necessary, or initials the Statement and makes it of record in connection with the present application.

The undersigned invites the Examiner to telephone the number provided below, if another telephone interview or clarification would be of assistance to the Examiner's review of this Statement.

Respectfully submitted,

/Mary C. Johnson, Reg. # 65,120/

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